

REMARKS

Co-pending Application

Applicants would like to direct the Examiner's attention to a co-pending application which is currently under examination, application serial number 09/997,450. Application serial number 09/997,450 was filed on the same day as the current application, November 30, 2001, and has one common inventor with the current application. Applicants respectfully submit that the Examiner may want to coordinate the examination of the current application with the above application.

Status of the Claims

In response to the Appeal Brief filed that was filed, the Examiner has re-opened prosecution.

Claims 1, 4 – 6, 8 – 10, 13, and 31 were pending. Claims 1, 4 – 6, 8 – 10, 13, and 31 have been rejected. Claim 6 has been amended to a more traditional Markush form. No new matter has been introduced, and no new issues have been raised. Claims 1, 4 – 6, 8 – 10, 13, and 31 will be pending upon entry of this amendment.

Reconsideration is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 1, 4 – 6, 8 – 10, 13, and 31 under 35 U.S.C. § 103(a) as being unpatentable over Taylor *et al.*, United States Patent No. 6,083,257 (Taylor), Ecer *et al.*, United States Patent No. 4,486,247 (Ecer) and Narayanan *et al.*, United States Patent No. 5,336,518 (Narayanan).

The Examiner's Position

The Examiner has alleged that Taylor discloses a metallic stent, in particular, a stent body of stainless steel, that is coated with a polymer coating, the polymer coating being in intimate contact with the tissue contacting surface of the stent.

The Examiner has admitted that Taylor does not disclose that the stent body has a carbon deposit. For the carbon deposits, the Examiner has cited Ecer. According to the Examiner, Ecer discloses “a stainless steel base material being modified by having carbon implanted within the

surface of the stainless steel base material at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface.” With citation to column 1, lines 14 – 18 of Ecer, the Examiner has further made the contention that Ecer discloses “carbon is a known material for increasing the hardness of steel.” The Examiner has also stated that “[i]t is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen.” Based upon the above, the Examiner has concluded that “it would have been obvious to one having ordinary skill in the art . . . to [have] provide[d] Taylor’s stainless steel stent body with a carbon deposit as taught by Ecer in order to provide the stent with the advantages described above.”

The Examiner has admitted that “Taylor as modified by Ecer fails to disclose the polymer film layer comprises an acrylate and is chemically bonded to the carbon deposit.” Therefore, the Examiner has cited Narayanan to cure these deficiencies. According to the Examiner, “Narayanan discloses a metallic stent comprising a polymer film,” and also that the films “. . . containing acrylate, such as HFBMA, enhance metallic surfaces with permanent improved biocompatibility.” The Examiner has then concluded that one of skill in the art would have applied the acrylate film as taught by Narayanan for improved biocompatibility. With respect to the covalent bonding to the carbon deposits, the Examiner has cited Applicants’ specification, which, in the Examiner’s view, discloses “. . . that depositing films to stents via plasma polymerization deposition is well known in the art,” and also that “one having ordinary skill in the art will recognize that some fragmentation of the acrylate typically occurs during the plasma polymerization deposition of the film layer, resulting in an acrylate-like polymer layer of fragmented acrylate, which will be covalently bonded to carbon deposits.” Thus, the Examiner has taken the position that the use of a plasma polymerization process to apply a polymer film “would yield a device in which the polymer film layer is covalently bonded to the carbon deposit as recited in the claims.”

The Examiner has also reiterated her position that claim 5 is treated as a product-by-process claim, and therefore the Examiner has not given much weight to the method of manufacture. With respect to claim 6, the Examiner has taken the position that “Narayanan discloses the activated acrylate may comprise functional groups such as carboxylate or amine,” where the Examiner has cited column 3, lines 43, 62, and 63 to support this position.

Regarding claim 10, the Examiner has also alleged that “Narayanan also teaches bioactive agents formed on the plasma polymerized polymer film . . . ,” and therefore, one would have formed “. . . a therapeutic substance on the modified film layer above as taught by Narayanan in order to enhance treatment and promote healing at the treatment site.”

Applicants’ Response

Applicants traverse the 35 U.S.C. § 103(a) rejection. The Examiner has not established a *prima facie* case of obviousness for the following reasons:

- (1) One of skill in the art would not have looked to Ecer as Ecer is non-analogous art
- (2) If one of skill in the art had looked at Ecer, one would not have combined Taylor and Ecer as the Examiner has proposed
- (3) The Examiner is using hindsight

(1) One of skill in the Art would not have looked to Ecer – Ecer is non-analogous art

Ecer is non-analogous art. As noted in the Manual of Patent Examining Procedure (MPEP), 8th Edition, § 2141.01, “to rely on a reference under 35 U.S.C. § 103, it must be analogous prior art.” Ecer is directed to “steels having high wear resistance and low friction surfaces” and methods for producing such steels. Ecer provides that exemplary uses for such steels are “machines having components, each having surfaces . . . which are in sliding, lubricated contact with each other under a load” (Ecer, column 3, lines 41 – 44) In the “Background” section of the patent, Ecer also discloses the following at column 1, lines 11 – 18:

In the past, the wear resistance of steel surfaces has been improved by subjecting the steel to a high temperature process in which a wear resistant coating is bonded to the surface or an element such as, carbon and/or nitrogen, is thermally diffused into the steel surface to locally increase the hardness of the steel itself in a relatively wide layer extending inwardly from the steel surface.

As noted above, Ecer is directed to wear and abrasion resistance of metallic parts as evidenced by the title of the invention, “Wear resistant steel articles with carbon, oxygen and nitrogen implanted in the surface thereof,” with the one reference to increasing the local hardness of steel by thermally diffusing carbon into the surface.

The Examiner has then taken the one statement in Ecer as the rationale for the citation of Ecer. However, MPEP § 2141.02 recites “[a] prior art reference must be considered in its

entirety, i.e., as a whole, . . . “ . *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).” The Examiner has taken the one statement out of context. When viewed as a whole, Ecer is clearly not in the same art as Applicants’ claimed invention, that is, implantable medical devices. Further, Ecer does not address the same problem as Applicants’ claims. Ecer addresses the problem of friction and wear resistance, which is in contrast to the problem that Applicants’ claimed invention addresses, the adherence of a polymeric layer to a metal substrate of an implantable medical device. When viewed as a whole, one of skill in the art would not have looked to Ecer as Ecer is directed to the issue of wear and abrasion resistance and is not in the field of medical devices.

In response to Applicants’ arguments, the Examiner has stated that “ . . . medical devices are formed of different materials in which wear and abrasion resistance are concerns of medical devices implanted within the body.” Applicants again fail to see the relevance of methods of improving wear and abrasion resistance of a metallic surface to the situation in which the metallic surface is to be coated with a polymer.

(2) One of Skill in the Art would not have combined Taylor and Ecer

In contrast to her earlier position that one would have modified Taylor to improve wear resistance as taught by Ecer, the Examiner has now taken the position that one would have modified the metallic stent of Taylor using the method of Ecer to improve the mechanical properties, specifically the tensile strength, stiffness, and resistance to radial compression, of a stent. The Examiner has reached this conclusion based upon one statement in the background section of Ecer, that is “ . . . an element such as, carbon and/or nitrogen, is thermally diffused into the steel surface to locally increase the hardness of the steel itself in a relatively wide layer extending inwardly from the steel surface.” (column 1, lines 14 – 18) (emphasis added)

It is Applicants’ position that one of skill in the art seeking to solve the problem of increasing the tensile strength, stiffness, and resistance to radial compression, of a stent, and in particular, a metallic stent, would not have utilized the method of Ecer as a means of achieving this goal. Clearly, Ecer only refers to locally increasing the hardness, that is increasing the hardness at the surface. To support this position, in the Response previously filed on October 23, 2009, Applicants submitted the §132 Declaration of Dr. Pamela Kramer-Brown, who is not an inventor of the present application. Dr. Kramer-Brown is an employee of Abbott Cardiovascular

Systems Inc., the owner of the present application. Dr. Kramer-Brown works in research and development of stent materials, and particularly, metals. The declaration of Dr. Kramer-Brown supports Applicants' position that one of skill in the art would not have used the method disclosed by Ecer to improve the mechanical properties of a stent.

The Examiner has not found Dr. Kramer-Brown's declaration to be convincing. It is the Examiner's position that "since some improvement may be observed, it is the examiner's position one having ordinary skill in the art may look to Ecer to modify Taylor to achieve such improvement." Moreover, the Examiner's assertion, "since some improvement may be observed," which does not appear to be based on any evidence, does not amount to a "reasonable expectation of success."

In sum, one of skill in the art would not have modified the stent of Taylor using the method of Ecer as has been suggested by the Examiner.

(3) The Examiner is using hindsight

It appears that the Examiner has interpreted a finding of obviousness to require no more than citation to references ostensibly disclosing the individual elements. However, this is not the legal basis for obviousness. According to the Supreme Court,

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR International Co. v. Teleflex Inc. et al., 127 S. Ct. 1727, 1741 (2007) It is recognized that this precedent also holds that there need not be a specific teaching, suggestion or motivation in the art. However, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (citations omitted)

In the present case, the Examiner has “found” the individual elements in different references, and then has used convoluted reasoning to combine them, such that the references, at least in the Examiner’s opinion, read on Applicants’ claims. The only reference even mentioning implantation of carbon, Ecer, is primarily directed to improving wear and abrasion resistance of metallic parts. The fact that the Examiner has taken a single sentence from the background of Ecer as the rationale for the combination of Ecer with Taylor is evidence that Applicants’ claims are not obvious.

Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicants respectfully request the allowance of pending claims 1, 4 – 6, 8 – 10, 13, and 31.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the Commissioner to charge any fees that may be required, or credit any overpayment to be made, to the **Squire, Sanders & Dempsey (US) LLP Deposit Account No. 07-1850**.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Dated: January 28, 2011
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